

Amendments to the Claims: This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

1. (Currently Amended) An aqueous formulation consisting essentially of, on a gram per 100 ml (reported as %) basis:

1-2 % 2,6-diisopropylphenol;

water; and up to 15% excipients, wherein said excipients consist essentially of up to 6% polyethylene glycol (PEG), up to 10% poloxamer 188, and optionally, one or more pH modifiers, stabilizers, or tonicity modifiers, and wherein said formulation is an aqueous solution including less than 1% lipids and being clear to the naked eye.

2-10. (Canceled)

11. (Previously Presented) The formulation of claim 1, wherein the total amount of said poloxamer 188 is about 5% to 10% of said formulation.

12. (Previously Presented) The formulation of claim 1, wherein the total amount of said poloxamer 188 is about 6% to 8% of said formulation.

13-19. (Canceled)

20. (Previously Presented) The formulation of claim 1, wherein the amount of 2,6-diisopropylphenol is about 1% of said formulation.

21-22. (Canceled)

23. (Previously Presented) The formulation of claim 1, wherein the total amount of PEG is less than 5% of said formulation.

24. (Previously Presented) The formulation of claim 1, wherein the total amount of PEG is between 2% and 6% of said formulation.

25. (Previously Presented) The formulation of claim 24 wherein the PEG is between 2% and 4% of said formulation.

26. (Previously Presented) The formulation of claim 1, wherein the total amount of PEG is between 3 and 4% of said formulation.

27. (Previously Presented) The formulation of claim 1, wherein said PEG is selected from the group consisting of PEG-300, PEG-400, PEG-600, PEG-800, and PEG-1000.

28. (Previously Presented) The formulation of claim 27, wherein said PEG is PEG-400.

29. (Previously Presented) The formulation of claim 1, wherein said excipients include propylene glycol and said propylene glycol is not more than 5% of said formulation.

30. (Previously Presented) The formulation of claim 29, wherein the amount of propylene glycol is not more than 2% of said formulation.

31. (Previously Presented) The formulation of claim 30, wherein the amount of propylene glycol is 1% to 2% of said formulation.

32. (Previously Presented) The formulation of claim 1, wherein said excipients include citric acid or a salt thereof.

33. (Previously Presented) The formulation of claim 32, wherein the concentration of said citric acid is in the range of from 2.5 to 15 mM.

34. (Previously Presented) The formulation of claim 32, wherein said formulation comprises citric acid in an amount of about 2 mg/ml.

35. (Previously Presented) The formulation of claim 1, wherein said excipients include an antimicrobial agent.

36. (Previously Presented) The formulation of claim 35, wherein said antimicrobial agent is selected from the group consisting of disodium edetate, metabisulfate, benzyl alcohol, cysteine or a salt thereof, and EDTA.

37. (Currently Amended) The formulation of claim 36, wherein said antimicrobial agent is benzyl alcohol in the an amount of up to 0.5% of said formulation.

38. (Canceled)

39. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount between 6 and 8% of said formulation; PEG-400 is present in an amount between 2 and 4% of said formulation; and the excipients include propylene glycol in an amount not greater than 2% of said formulation.

40. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 8% of said formulation; PEG-400 is present in an amount of about 4% of said formulation; propylene glycol is present as an excipient in an amount of about 1% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation.

41. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 8% of said formulation; PEG-400 is present in an amount of about 3% of said formulation; propylene glycol is present as an excipient and in an amount of about 1% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation.

42. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 7% of said formulation; PEG-400 is present in an amount of about 4% of said formulation; propylene glycol is present as an excipient in an amount of about 1% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation.

43. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 7% of said formulation; PEG-400 is present in an amount of about 3% of said formulation; propylene glycol is present, as an excipient, in an amount of about 1% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation.

44. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 6% of said formulation; PEG-400 is present in an amount of about 4% of said formulation; propylene glycol is present, as an excipient, in an amount of about 1% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation.

45. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 6% of said formulation; PEG-400 is present in an amount of about 4% of said formulation; propylene glycol is present, as an excipient, in an amount of about 2% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation.

46. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 6% of said formulation; PEG-400 is present in an amount of about 6% of said formulation; propylene glycol is present, as an excipient, in an amount of about 1% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation.

47. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 8% of said formulation; PEG-400 is present in an amount of about 2% of said formulation; propylene glycol is present, as an excipient, in an amount of about 1% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation.

48. (Previously Presented) The formulation of claim 28, wherein poloxamer 188 is present in an amount of about 7% of said formulation; PEG-400 is present in an amount of about 2% of said formulation; propylene glycol is present, as an excipient, in an amount of about 1% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation.

49. (Currently Amended) An aqueous formulation consisting essentially of, on a gram per 100 ml (hereafter %) total formulation basis:

- a. 2,6-diisopropylphenol;
- b. water, and
- c. up to 15% excipients, wherein said excipients consist essentially of poloxamer 188 in an amount of less than 10% of said formulation, a polyethylene glycol in an amount of between 2% and 4% of said formulation, and optionally, one or more pH modifiers, stabilizers, or tonicity modifiers, and wherein the formulation includes less than 1% lipids and the formulation includes no other glycol or alcohol and is clear to the naked eye.

50. (Previously Presented) The formulation of claim 49, wherein said poloxamer 188 is present in an amount of between 5% to 9% (w/v) of said formulation; and said polyethylene glycol is PEG-400, present in an amount of between 2% and 4% (w/v) of said formulation.

51. (Previously Presented) The formulation of claim 50, wherein said poloxamer 188 is present in an amount of about 8% (w/v) of said formulation; PEG-400 is present in an amount of about 4% (w/v) of said formulation; and 2,6-diisopropylphenol in an amount of about 1% (w/v) of said formulation, wherein said formulation is substantially free of propylene glycol.

52. (Previously Presented) The formulation of claim 50, wherein said poloxamer 188 is present in an amount of about 8% of said formulation; PEG-400 is present in an amount of about 3% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation, wherein said formulation is substantially free of propylene glycol.

53. (Previously Presented) The formulation of claim 50, wherein said poloxamer 188 is present in an amount of about 7% of said formulation; PEG-400 is present in an amount of about 4% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation, wherein said formulation is substantially free of propylene glycol.

54. (Previously Presented) The formulation of claim 50, wherein said poloxamer 188 is present in an amount of about 7% of said formulation; PEG-400 is present in an amount of about 3% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation, wherein said formulation is substantially free of propylene glycol.

55. (Previously Presented) The formulation of claim 50, wherein said poloxamer 188 is present in an amount of about 9% of said formulation; PEG-400 is present in an amount of about 2% of said formulation; and 2,6-diisopropylphenol is present in an amount of about 1% of said formulation.

56. (Previously Presented) The formulation of claim 50, wherein said poloxamer 188 is present in an amount of 8% of said formulation; and PEG-400 is present in an amount of 2% of said formulation.

57. (Previously Presented) The formulation of claim 50, wherein said poloxamer 188 is present in an amount of 7% of said formulation; and PEG-400 is present in an amount of 2% of said formulation.

58. (Previously Presented) The formulation of claim 49, further comprising, in the excipient portion thereof, citric acid or a salt thereof.

59. (Previously Presented) The formulation of claim 58, wherein said citric acid is at a concentration between 2.5 and 10 mM.

60. (Previously Presented) The formulation of claim 49, further comprising, in the excipient portion thereof, an antimicrobial agent.

61. (Previously Presented) The formulation of claim 60, where said antimicrobial agent is benzyl alcohol.

62. (Previously Presented) The formulation of claim 1 or claim 49, wherein said formulation further comprises, in the excipient portion thereof, polysorbate.

63. (Previously Presented) The formulation of claim 62, further including in the excipient portion thereof, polyoxyethylene 20 sorbitan monooleate in an amount of 0.5 to 15 percent of said formulation; propylene glycol in an amount of 0.5 to 15 percent of said formulation; PEG-400 in an amount of 1 to 20 percent of said formulation; and poloxamer 188 in an amount of 2 to 15 percent of said formulation.

64. (Previously Presented) The composition of claim 1 or claim 49, wherein said poloxamer 188 is purified poloxamer 188, wherein said purified poloxamer has a polydispersity value of between 5 and 1, 4 and 1, 3 and 1, 2 and 1, or 1.1 and 1.

65. (Canceled)

66. (Currently Amended) An aqueous formulation, consisting essentially of, on a gram per 100 ml (reported as %) total formulation basis:

- a) a block copolymer in an amount of less than 10% of said formulation;
- b) a polyethylene glycol in an amount of between 2% and 6% of said formulation;

- c) 2,6-diisopropylphenol;
- d) water;
- e) optionally citric acid or a salt thereof; and
- f) optionally an antimicrobial agent

said components a, b, e, and f comprising excipients of said formulation, said excipients, in total, not exceeding 15% of said formulation, said formulation not exceeding 1% lipids and being clear to the naked eye.

67. (Previously Presented) The formulation of claim 66, wherein said citric acid or a salt thereof comprises citric acid.

68. (Previously Presented) The formulation of claim 66, wherein the excipients of said formulation include an antimicrobial agent.

69-70. (Canceled)

71. (Currently Amended) A microemulsion, consisting essentially of:

- a) poloxamer 188;
- b) a polyethylene glycol (PEG);
- c) 2,6-diisopropylphenol;
- d) propylene glycol; and
- e) water,

said components a, b, and d comprising excipients and said excipients not exceeding 15% grams per 100 ml of said formulation, said microemulsion being lipid-free comprising less than 1% lipid and being clear to the naked eye.

72. (Previously Presented) An aqueous formulation, consisting essentially of (on a weight/volume grams/100 ml % basis):

- a) poloxamer 188 in an amount of less than 10% of said formulation;
- b) a polyethylene glycol in an amount of between 2% and 4% of said formulation;
- c) 2,6-diisopropylphenol; and
- d) water;

said components a and b comprising no more than 15% of said formulation, wherein said formulation has an average particle size of less than about 65 nanometers.

73. (Previously Presented) A method of inducing or maintaining anesthesia in a mammal, comprising administering to said mammal an amount of a formulation, as claimed in any one of claims 1, 49, 75 or 66, effective to induce or maintain anesthesia.

74. (Previously Presented) A multi-use container, comprising the formulation as claimed in any one of claims 1, 49, 66, or 75.

75. (Currently Amended) A formulation comprising a injectable anesthetic solution, including citric acid and an antimicrobial agent as optional components, said formulation including no more than 15% (weight/volume grams/100 ml) excipients and consisting essentially of, in addition to said optional components, a clear aqueous composition selected from the group consisting of:

- a) 1% propofol, 9% poloxamer 188, 2% PEG 400, and water;
- b) 1% propofol, 8% poloxamer 188, 4% PEG 400, and water;
- c) 1% propofol, 8% poloxamer 188, 4% PEG 400, 1% propylene glycol, and water;
- d) 1% propofol, 8% poloxamer 188, 3% PEG 400, and water;
- e) 1% propofol, 8% poloxamer 188, 3% PEG 400, 1% propylene glycol, and water;
- f) 1% propofol, 7% poloxamer 188, 4% PEG 400, and water; and

g) 1% propofol, 7% poloxamer 188, 4% PEG 400, 1% propylene glycol, and water, wherein said formulation includes less than 1% lipids.

76. (Previously Presented) The formulation of claims 1 or 49 wherein said pH modifiers are selected from the group consisting of sodium hydroxide, potassium hydroxide, and hydrochloric acid.

77. (Currently Amended) An aqueous formulation consisting essentially of:

a) 2,6-diisopropylphenol; and

b) water; and

c) up to 15% excipients, wherein said excipients consist essentially of, on a gram per 100 mL total formulation basis, 8% poloxamer 188, 3% polyethylene glycol 400, 1% propylene glycol, 0.2% citric acid monohydrate, a preservative, and sodium hydroxide, and wherein said formulation is clear to the naked eye and includes less than 1% lipids.

78. (Previously Presented) The formulation of any of claims 1, 49, 66, 71, 75, or 77 having an average particle size of from 30 to 75 nanometers.